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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,641	06/11/2001	Cato T. Laurencin	DRE-0055	2890

26259 7590 03/25/2003

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

Office Action Summary

Application No. 09/878,641		Applicant(s) LAURENCIN ET AL.	
Examiner Urmi Chattopadhyay		Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 1/2/03 has been entered as Paper No. 9. Changes to the specification and claims have been approved by the Examiner.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al. in view of Hlavacek et al.

Vacanti et al. discloses a replacement construct and method for producing a graft material composed of living cells in a degradable matrix with all the elements of claims 1 and 8, respectively, but is silent to the scaffold being braided. See columns 6-7, lines 57-18 for harvesting, growing and passaging cells in tissue culture, and column 3, lines 13-14, 42-44 and 52-57, column 4, lines 1-25, column 2, lines 52-53 and abstract for seeding the cultured cells on a degradable, porous, polymeric fiber-based, three-dimensional scaffold. Hlavacek et al. teaches a ligament or tendon replacement construct comprising a degradable, polymeric fiber-based (column 4, lines 57-65), three-dimensional scaffold that is braided (column 5, lines 13-14) in order for the implant to have the desired strength and stiffness in the primary (axial) loading

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direction. See column 6, lines 39-51. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Hlavacek et al. to make the degradable, porous, polymeric fiber-based, three-dimensional scaffold of Vacanti et al. braided in order to impart the desired strength and stiffness in the primary (axial) loading direction.

Claims 9-11, see column 6, lines 35-40 and 50-53 for specific cells.

4. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hlavacek et al. in view of Vacanti et al. (USPN 5,855,610).

Hlavacek et al. discloses a braided ligament or tendon implant with all the elements of claim 2, but is silent to the degradable polymeric fiber-based, three-dimensional braided scaffold being seeded with cells, ingrowth of which is supported by the scaffold. Vacanti et al. teaches a replacement construct comprising a degradable, polymeric fiber-based, three-dimensional scaffold (see abstract, column 3, lines 42-44, column 4, lines 1-25) seeded with cells (column 2, lines 52-53), ingrowth of which is supported by the scaffold (column 3, lines 22-23). Examiner contends that seeding the scaffold with cells, specifically *in vitro*, provides for a more rapid development and differentiation process for the tissue being formed, and it is clear that cellular differentiation and the creation of tissue specific extracellular matrix is critical for the engineering of a functional implant. Seeding cells onto the scaffold prior to implantation also provides the scaffold with greater strength when the cells proliferate, which allows for the scaffold to endure the *in vivo* forces that act upon it once implanted. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Vacanti et al. to modify the ligament or tendon implant of Hlavacek et al. to seed

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the polymeric scaffold with cells in order for a more rapid development and differentiation process of the tissue being formed and added strength to the scaffold prior to implantation.

Vacanti et al. also teaches the limitations of claims 3-5, which require the cells be mesenchymal in origin, generate mesenchymal cells and be pluripotent stem cells, respectively. See column 6, lines 35-40 and 50-53. It would have been obvious to one of ordinary skill in the art to modify the implant of Hlavacek et al. by seeding the scaffold with cells that are mesenchymal in origin, say fibroblasts, in order to form a ligament replacement construct or with pluripotent stem cells because they are immunologically inert.

With respect to claim 6, Hlavacek et al. teaches a method of repairing, replacing or reconstructing a damaged tendon or ligament in a patient comprising implanting at a damaged tendon or ligament a replacement construct, but is silent to the replacement construct being porous. See column 8, lines 55-59 for the method of replacing a damaged ligament. Vacanti et al. teaches the additional limitation of making the degradable, polymeric fiber-based, three-dimensional braided scaffold porous in order to allow for vascular ingrowth. See column 3, lines 53-54. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Vacanti et al. to make the replacement construct in the method of Hlavacek et al. porous in order to allow for vascular ingrowth.

Claim 7, see rejection to claim 2, supra, and column 8, lines 55-59 for Hlavacek et al. disclosing the method of replacing a damaged ligament.

Response to Arguments

5. Applicant's arguments filed 1/2/03 have been fully considered but they are not persuasive.
6. With respect to the rejection of claims 2-5, 7 and 8-11, applicant argues that the combination of references provides no reasonable expectation of success that a braided matrix of the present invention merely seeded with cells and not implanted to form extracellular matrix would provide a useful graft material or replacement construct. Examiner would like to direct applicant's attention to the abstract, as cited above, for the option of seeding the matrix at the time of reimplantation. According to this option, the matrix formed of polymer fibers having a particular desired shape is implanted subcutaneously. The implant is then surgically retrieved and one or more defined cell types are distributed onto and into the fibers. The seeded matrix is then implanted at the desired site. Following this method, it is apparent that there is a reasonable expectation of success because the extracellular matrix is formed and then seeded to provide a useful graft material or replacement construct. Examiner would also like applicant to note that neither the product claims, nor the method claims of the current invention preclude the step of implanting a braided matrix to form extracellular matrix prior to seeding. For these reasons, the claim rejections based on the cited prior art are maintained.

Conclusion

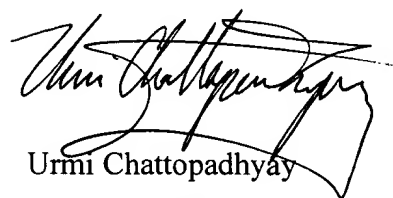
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

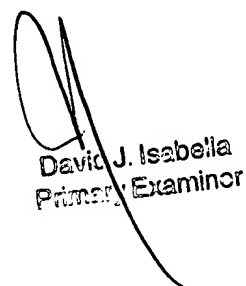


Urmi Chattopadhyay

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March 17, 2003


David J. Isabella
Primary Examiner